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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/784,031

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Cory Schaffhausen

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EXAMINER

BACHMAN, LINDSEY MICHELE

ART UNIT

PAPER NUMBER

3734

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/784,031	Applicant(s) SCHAFFHAUSEN, CORY	
	Examiner LINDSEY BACHMAN	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 20 and 22-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 20 and 22-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 February 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>12-28-07</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 28 December 2007 has been entered.

Response to Arguments

Applicant's arguments filed 28 December 2007 have been fully considered but they are not persuasive. Applicant argues that the rejections under Sikora in view of Oberlander in further view of Bojarski are improper because Oberlander teaches away from having any anchors on the outer surface of tissue when stating "at least partially and preferably completely in the meniscal tissue." Applicant's arguments are not persuasive because the rejection is modifying Sikora with teachings by Oberlander, not modifying Oberlander with teachings by Sikora. Further, references are not limited to their preferred embodiment; because Sikora and Oberlander teach that it is known to place both anchors within tissue or on the outside of the tissue, it would be obvious to have one anchor within tissue and one anchor on the outside of the tissue. Also, the claim would have been obvious because the technique for improving the method of

closing a meniscal tear was part of the ordinary capabilities of a person of ordinary skill in the art in view of the teaching for improvement in other situations.

Information Disclosure Statement

The information disclosure statement filed 28 December 2007 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Cases missing include: citation numbers BB, BC, BD, BS, BT, BU, BV, BW, BX, BY, BZ, and CA on the IDS submitted 28 December 2008 have not been considered.

Claim Rejections - 35 USC § 112

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 claims "a blunt end of a hollow tube" in lines 3-4. Claim 6, which depends from Claim 4, again claims "a blunt end of a hollow tube" in lines 1-2. It is unclear whether Applicant is intending to claim another hollow tube with a blunt end in Claim 6, or if Applicant is referring back to the hollow tube with a blunt end in Claim 4. For the purpose of examination, it will be assumed that Applicant is referring back to the

blunt end of a hollow tube initially claimed in Claim 4 because only one tube with a blunt end is disclosed in Applicant's specification and drawings.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claim 1-3, 7, 20, and 22-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sikora et al. (US Patent Application 2002/0019649) in further view of Oberlander (US Patent 5,702,462) and Bojarski et al (US Patent Application 2003/0130694).

Claim 1: Sikora'649 teaches a method for closing a tissue wound that includes inserting a needle (1070) containing a retaining head (1012) from a first insertion position (1060a) on a first outer surface of the body tissue, through the tear (1052) and to a second outer surface (1058) of the body tissue; ejecting the retaining head (1012)

from the needle (1070) wherein the retaining head (1012) grasps the second outer surface (1058) in an engaged position (paragraph [0152]); advancing an anchor (1014) coupled to the retaining head (1012) (paragraph [0147], lines 1-2) from a second insertion position (1060b) on first outer surface of the body to a position through a portion of the tear (1052) (paragraph [0153]), said anchor (1014) coupled to the retaining head by a flexible member that extends a distance along the first outer surface of the body tissue from said first insertion position to said second insertion position (see Figure 1, element 10b).

Sikora'649 does not teach that the anchor is placed between the tear and the outer portion of the body tissue. Further, Sikora'649 does not teach that the retaining head and anchor are attached by the terminal end of the flexible member.

Oberlander'462 teaches that an anchor (11b) is placed within the body tissue (31) in a location that is between a tear (31d) and an outer portion of the body tissue (31b) (see Figures 5, 8 and 9) because this is said to enhance the repair of the body tissue since the anchor (11b) is implanted in the thicker part of the tissue (column 4, lines 3-34).

Bojarski'694 teaches that it is known in a method of repairing a meniscus to have a retaining head (1005) and an anchor (1010) that are attached at the terminal ends of a suture (1097) because it allows the surgeon to create tension in the suture by placing the retaining head and anchor a certain distance apart (paragraph [0151]-[0155]). This tension also causes the retaining head and anchor to shift to a direction that is perpendicular to the suture and apposes the meniscal tear. It would have been obvious

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to modify the method taught by Sikora'649 as taught by Bojarski'694 with a single suture that is attached by its terminal ends to a retaining head and anchor in order to create tension in the two anchors only by placing the terminal ends apart because this allows the surgeon to automatically tighten the suture without the need for the surgeon to additionally agitate and access the surgical site.

Claim 2: Sikora'649 teaches a method that includes ejecting the retaining head (1012) further includes advancing a plunger within the needle (1070) towards a distal opening of the needle, deploys the retaining head (1012) through the distal opening of the needle (1070), and removing the needle from the body tissue at opening first insertion portion (1060a) (see paragraph [0152]).

Claim 3: Sikora'649 teaches a slit (1076) and attaching the flexible member to an appendage of anchor that protrudes through the slit and holding it while releasing the anchor (paragraph [0146]).

Claim 7: Sikora'649 teaches that ejecting the retaining head is performed simultaneously with advancing the anchor (paragraph [0150] and [151]).

Claim 20: Sikora'649 teaches a method of repairing a tear in a body tissue that includes a passing a needle (1070) from a first portion of the body tissue through the tear (1052) and to an outer surface of the body tissue (1058); ejecting a retaining head (1012) from the needle (1070) so that the retaining head (1012) lies against the outer surface (1058) in an engaged position (paragraph [0152]); and inserting an anchor (1014) coupled to the retaining head (1012) (paragraph [0147], lines 1-2) by a flexible

member (1016) from a first portion through the tear to a desired location (paragraph [0153]).

Sikora'649 does not teach that the anchor is placed between the tear and the outer portion of the body tissue. Further, Sikora'649 does not teach that the retaining head and anchor are attached by the terminal end of the flexible member.

Oberlander'462 teaches that an anchor (11b) is placed within the body tissue (31) in a location that is between a tear (31d) and an outer portion of the body tissue (31b) (see Figures 5, 8 and 9) because this is said to enhance the repair of the body tissue since the anchor (11b) is implanted in the thicker part of the tissue (column 4, lines 3-34). It would have been obvious to one skilled in the art at the time the invention was made to modify the method taught by Sikora'649 by placing the anchor between the tear and the outside of the body tissue because placing the anchor within the body tissue aids in enhancing the effectiveness of the repair.

Bojarski'694 teaches that it is known in a method of repairing a meniscus to have a retaining head (1005) and an anchor (1010) that are attached at the terminal ends of a suture (1097) because it allows the surgeon to create tension in the suture by placing the retaining head and anchor a certain distance apart (paragraph [0151]-[0155]). This tension also causes the retaining head and anchor to shift to a direction that is perpendicular to the suture and apposes the meniscal tear. It would have been obvious to modify the method taught by Sikora'649 as taught by Bojarski'694 with a single suture that is attached by its terminal ends to a retaining head and anchor in order to create tension in the two anchors only by placing the terminal ends apart because this

allows the surgeon to automatically tighten the suture without the need for the surgeon to additionally agitate and access the surgical site.

Sikora'649 does not teach that the retaining head and anchor are attached by the terminal end of the flexible member.

The two anchoring elements (11a, 11b) are each connected to a terminal end of a suture (15). The sutures are then tied together, which connects the two device together which connects the two members by a terminal end of a suture (column 4, lines 3-34) in order to create tension in the suture and pull the torn tissue together. It would have been obvious to one skilled in the art at the time the invention was made to modify the method taught by Sikora'649 by connecting the two sutures in order to create a tension in the suture that brings the two side of the tissue tear together.

Claim 22: Sikora'649 teaches that the flexible member (1016) is taught between the anchor (1014) and the retaining head (1012) (paragraph [0153]). Regarding the structure of the retaining head, anchor and their attachment to the flexible member: it has been held that to be entitled to weight in method claims, the recited structure limitations therein must affect the method in a manipulative sense, and not to amount to the mere claiming of a use of a particular structure. Further, Oberlander'462 teaches that it is known to attach a flexible member at one location on either the anchor or retaining head (see Figure 2). The limitation of molding the flexible member to the anchor is a product-by-process limitation. The anchor/retaining head taught by Oberlander'462 has the same product as claimed by Applicant (column 3, lines 38-53).

Claim 23: Sikora'649 teaches advancing a plunger (1080) within the needle (1070) towards a distal opening of the needle (direction A, Figure 20), deploying the retaining head (1012) from the distal opening and removing the needle (1070) from the body tissue (paragraph [0152]).

Claim 24: Sikora'649 teaches a slit (1076) and attaching the flexible member to an appendage of anchor that protrudes through the slit and holding it while releasing the anchor (paragraph [0146]).

Claim 25: Sikora'649 teaches that advancing the anchor includes advancing a plunger within the hollow tube a predetermined distance t to advance anchor (1014) to a desired location (paragraph [0153]).

Claim 26: Sikora'649 teaches that the first portion of the body tissue is a first outer surface of the meniscus (paragraph [0151], Figure 20).

Claim 27: Sikora'649 teaches a method of repairing a tear in a meniscus that includes inserting a cannulated piercing member (1070) with a piercing end (1074) containing a retaining head (1012) therein from a first insertion position on a first outer surface of the meniscus through the tear (1052) and to a second outer surface of the meniscus (1058) (paragraph [0151]), where the retaining head (1012) has a longitudinal body and is positioned longitudinally within the cannulated piercing member (1070) (paragraph [0015]); ejecting the retaining head (1012) from the piercing member (1070) so that the head engages with the second outer surface (1058) (paragraph [0152]); and advancing an anchor (1014) coupled to retaining head (1012) from a second insertion position (1060b) on the first outer surface of the meniscus to an implanted position (at

side 1058), wherein when in the implanted position (at side 1058) the anchor passes through a portion of the tear (1052); further the anchor (1014) is coupled to the retaining head (1012) (paragraph [0005]) that extends a distance along the first outer surface of the meniscus (Figure 20, paragraph [0153]).

Sikora'649 does not teach that the anchor is placed between the tear and the outer portion of the body tissue. Further, Sikora'649 does not teach that the retaining head and anchor are attached by the terminal end of the flexible member.

Oberlander'462 teaches that an anchor (11b) is placed within the body tissue (31) in a location that is between a tear (31d) and an outer portion of the body tissue (31b) (see Figures 5, 8 and 9) because this is said to enhance the repair of the body tissue since the anchor (11b) is implanted in the thicker part of the tissue (column 4, lines 3-34). It would have been obvious to one skilled in the art at the time the invention was made to modify the method taught by Sikora'649 by placing the anchor between the tear and the outside of the body tissue because placing the anchor within the body tissue aids in enhancing the effectiveness of the repair.

Bojarski'694 teaches that it is known in a method of repairing a meniscus to have a retaining head (1005) and an anchor (1010) that are attached at the terminal ends of a suture (1097) because it allows the surgeon to create tension in the suture by placing the retaining head and anchor a certain distance apart (paragraph [0151]-[0155]). This tension also causes the retaining head and anchor to shift to a direction that is perpendicular to the suture and apposes the meniscal tear. It would have been obvious to modify the method taught by Sikora'649 as taught by Bojarski'694 with a single

suture that is attached by its terminal ends to a retaining head and anchor in order to create tension in the two anchors only by placing the terminal ends apart because this allows the surgeon to automatically tighten the suture without the need for the surgeon to additionally agitate and access the surgical site.

Claim 28: Sikora'649 teaches that ejecting the retaining head (1012) from the piercing member (1070) includes advancing a plunger (1080) within the piercing member (1070) towards a distal opening (1074) of the piercing member (1070); deploying the retaining head from the distal opening (1074) and removing the piercing member from the meniscus at the first insertion position (paragraph [0152]).

Claim 29: Sikora'649 teaches a slit (1076) and attaching the flexible member to an appendage of anchor that protrudes through the slit and holding it while releasing the anchor (paragraph [0146]).

Claims 4-6 are rejected under under 35 U.S.C. 103(a) as being unpatentable over Sikora'649 in view of Oberlander'462 and Bojarski'694 and in even further view of Richards et al. (US Patent 4,669,473) and Clark (US Patent 5,954,747)

Claim 4 and 6: Sikora in view of Oberlander in further view of Bojarski do not teach the use of a second tubular member to deploy the second fastening device (anchor).

Richards'473 teaches that it is known to connect a piercing member (405) and a hollow tube (406) via a cross-bar (443) in order to align the front tips of the piercing member and the hollow tube (column 7, lines 55-64). This also separates the two members carrying anchors/retaining heads by a pre-determined distance. It would have

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been obvious to one skilled in the art at the time the invention was made to modify the device used in the method taught by Sikora'649 and Oberlander'462 and Bojarski'694 as taught by Richards'473 by connecting the piercing member and hollow tube so that the tips are aligned.

Sikora in view of Oberlander in further view of Bojarski and Richard'473 do not teach the use of a blunt tip in order to not penetrate body tissue while deploying an anchor.

Clark'747 teaches that it is known to perform meniscal repair with an anchor (44) that is deployed from a hollow tube (54) having a blunt tip (64) and the blunt tip does not penetrate the meniscus (see Figures 10a-10f) because the blunt tip is used to push the meniscal tissue on opposite sides of the tear together without penetration (column 5, lines 15-18). It would have been obvious to modify the device taught by Sikora in view of Oberlander in further view of Bojarski and Richard'473 with the blunt end taught by Clark'747 in order to push the meniscal tissue together without penetration.

Claim 5: Sikora'649 teaches a slit (1076) and attaching the flexible member to an appendage of anchor that protrudes through the slit and holding it while releasing the anchor (paragraph [0146]).

Claims 30-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sikora'649 in view of Oberlander'462 and Bojarski'694 and in even further view of Stevens et al. (US Patent 5,462,560) and Clark (US Patent 5,954,747)

Claims 30-32: Sikora in view of Oberlander in further view of Bojarski do not teach the use of a second tubular member to deploy the second fastening device (anchor).

Stevens'560 teaches that it is known to connect a piercing member (72) and a hollow tube (74) via a cross-bar (76). Further, Stevens'560 teaches that the hollow tube has a length that is shorter than the length of the piercing member (see Figure 1 and column 2, lines 50-62) because it makes it easier to secure the tissue. This also separates the two members carrying anchors/retaining heads by a pre-determined distance. It would have been obvious to one skilled in the art at the time the invention was made to modify the device used in the method taught by Sikora'649 and Oberlander'462 and Bojarski'694 as taught by Stevens'560 by attaching the hollow tube and the piercing member in order to make it easier for the surgeon to hold the device during the procedure.

Sikora in view of Oberlander in further view of Bojarski and Stevens'560 do not teach the use of a blunt tip in order to not penetrate body tissue while deploying an anchor.

Clark'747 teaches that it is known to perform meniscal repair with an anchor (44) that is deployed from a hollow tube (54) having a blunt tip (64) and the blunt tip does not penetrate the meniscus (see Figures 10a-10f) because the blunt tip is used to push the meniscal tissue on opposite sides of the tear together without penetration (column 5, lines 15-18). It would have been obvious to modify the device taught by Sikora in view

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of Oberlander in further view of Bojarski and Stevens with the blunt end taught by Clark'747 in order to push the meniscal tissue together without penetration.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LINDSEY BACHMAN whose telephone number is (571)272-6208. The examiner can normally be reached on Monday to Thursday 7:30 am to 5 pm, and alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on 571-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kevin T. Truong/
Primary Examiner, Art Unit 3734
/L. B./

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